Excimer Laser Photorefractive Keratectomy for Presbyopia: 24-month Follow-up in Three Eyes

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ABSTRACT

BACKGROUND: For some patients, standard optical correction for presbyopia is not satisfactory. Using a specially designed mask, we developed a procedure for correcting presbyopia with excimer laser photorefractive keratectomy (PRK).

METHODS: A mask consisting of a mobile diaphragm formed by two blunt blades was used to ablate a 10 to 17 μm deep semilunar-shaped zone immediately below the pupillary center, steepening the corneal curvature in that area. Three eyes of three presbyopic patients were treated, aiming at a near addition of +3.00 D. Follow-up time was 24 months.

RESULTS: After an initial regression of 1.00 D during the first 6 months, the presbyopic correction remained stable for the duration of the follow-up period, enabling uncorrected near vision of J3 in all three eyes. Uncorrected distance visual acuity was not altered. Contrast sensitivity (Regan) was slightly decreased only at the 11% level. Videokeratography confirmed corneal steepening in the ablated area.

CONCLUSION: The visual and refractive outcome of excimer laser PRK for presbyopia with the Aesculap-Meditec MEL 60 is promising, especially in view of the 2-year follow-up. [*J Refract Surg* 1998;14:31-37]

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Received: May 14, 1996
Accepted: September 2, 1997

Presbyopia is a major refractive problem in the aging population, and for some people standard optical correction is not satisfactory.[1] In some presbyopic eyes treated with refractive surgery, useful reading vision is present despite emmetropia.[2,3] We performed zonal excimer laser photorefractive keratectomy (PRK) in three eyes of three presbyopic patients. Using a specially designed mask, the corneal curvature was steepened immediately below the pupillary center.

PATIENTS AND METHODS

Two females (ages 59 and 55 yr) and one male (age 62 yr) were recruited for the study. Their presbyopia had been stable for at least 1 year, and corneal astigmatism was less than 0.50 diopters (D).

The eyes underwent a comprehensive ophthalmological examination, including near and distance visual acuity and manifest refraction (Table 1), cycloplegic refraction, contrast sensitivity, videokeratography, tonometry, slit-lamp and fundus examinations. No pathology was found.

The Aesculap-Meditec MEL 60 excimer laser (Aesculap Meditec GmbH, Heroldsberg, Germany) was used. The 193-nm unit had a repetition rate of 20 Hz, a fluence of 235 mJ/cm^2, a rectangular-shaped 1.5 x 8.0 mm beam, and a scanning speed of 5.3 mm/sec.

The procedure was performed with an instrument designed by one of the authors (GNM), consisting of a fixation suction ring and a mask. The mask (Fig 1) consists of a mobile diaphragm formed by two blunt blades, one with a concave edge, the other with a convex one. The blades, which exhibit different radii of curvature, can slide over each other. Once the mask is affixed in place by suction, it can be moved along the X-Y axis with the aid of two wheels (Fig 1, N° 1 and N° 2). This

Table 1
Visual Acuity and Refractive Data for Three Eyes of Three Patients during 24 Months after PRK for Presbyopia

Sex, Age (yr)	Baseline	Time after Surgery						
		1 w	2 w	1 mo	3 mo	6 mo	12 mo	24 mo
Female, 59								
Cycloplegic refraction (D)	+0.50	+0.50	+0.50	+0.50	+0.50	+0.50	+0.50	+0.50
Uncorrected visual acuity	20/20	20/20	20/20	20/20	20/20	20/20	20/20	20/20
Uncorrected near visual acuity (Jaeger)	9	1	1	1	1	2	3	3
Spectacle-corrected near visual acuity (Jaeger)	1	1	1	1	1	1	1	1
and near refraction (D)	+3.00	0	0	0	0	+1.00	+1.00	+1.00
Haze (grade)	-	0.5	0.5	1	0	0	0	0
Male, 62								
Cycloplegic refraction (D)	+1.50	+1.50	+1.50	+1.50	+1.50	+1.50	+1.50	+1.50
Uncorrected visual acuity	20/25	20/25	20/25	20/25	20/25	20/25	20/25	20/25
Spectacle-corrected visual acuity	20/20	20/20	20/20	20/20	20/20	20/20	20/20	20/20
(refraction, D)	+1.00	+1.00	+1.00	+1.00	+1.00	+1.00	+1.00	+1.00
Uncorrected near visual acuity (Jaeger)	none	2	2	2	3	3	3	3
Spectacle-corrected near visual acuity (Jaeger)	1	1	1	1	1	1	1	1
and near refraction (D)	+4.00	+1.25	+1.25	+1.25	+1.50	+1.50	+1.50	+1.50
Haze (grade)	-	0.5	0.5	1	0	0	0	0
Female, 55								
Cycloplegic refraction (D)	-0.50	-0.50	-0.50	-0.50	-0.50	-0.50	-0.50	-0.50
Uncorrected visual acuity	20/70	20/70	20/70	20/70	20/70	20/70	20/70	20/70
Spectacle-corrected visual acuity	20/20	20/20	20/20	20/20	20/20	20/20	20/20	20/20
(refraction, D)	-1.00	-1.00	-1.00	-1.00	-1.00	-1.00	-1.00	-1.00
Uncorrected near visual acuity (Jaeger)	4	1	1	1	2	2	2	2
Spectacle-corrected near visual acuity (Jaeger)	1	1	1	1	1	1	1	1
and near refraction (D)	+1.50	0	0	0	+0.50	+0.50	+0.50	+0.50
Haze (grade)	-	0.5	0.5	0.5	0	0	0	0

allows the necessary flexibility in positioning the fixation ring from the pupillary center to the corneal center. In this way, adjustment can be made to assure centration and a reproducible ablation zone size (Fig 2).

When the mask's diaphragm is slowly closed under the excimer beam, a semilunar zone is ablated. The very shape of the zone is designed to protect the pupillary area. The semilunar-shaped zone is of variable depth, with a greater central depth, and a centrifugal decrease of depth toward the untreated cornea (Fig 2).

Although this ablation pattern is deeper in the center than in the periphery (similar to the pattern in PRK for myopia), one still obtains a reduction in hyperopia (presbyopia). The reason for this apparently paradoxical optical effect is that only the superior part of the semilunar zone (the part in which the curvature is steepened) acts to correct the hyperopia; only the rays that pass through the pupil have an optical effect.

Before ablation is commenced, the superior blade of the mask is closed to protect the pupil, so that its lower edge is 1.0 mm below the center of the pupil. Then, starting from 1.0 mm below the pupillary center, two consecutive curvatures are created through a variable number of scans (ablation rate 1 μm/scan).

Each of these curvatures is 2 mm long and subtends an angle of 15°. The first curvature (A) represents the steepening created by the laser ablation. "A" is the curvature responsible for the desired optical effect. The second curvature (B) represents the transition to the untreated cornea (Fig 3).

Figure 4 shows the basis for the calculations.

In each patient, only one eye was treated. The surgical procedure was preceded by topical anesthesia with ossibuprocaine 0.4% and the marking of the center of the entrance pupil, in the same manner as in radial keratotomy. A special marker was then used to delineate the treatment area. After the

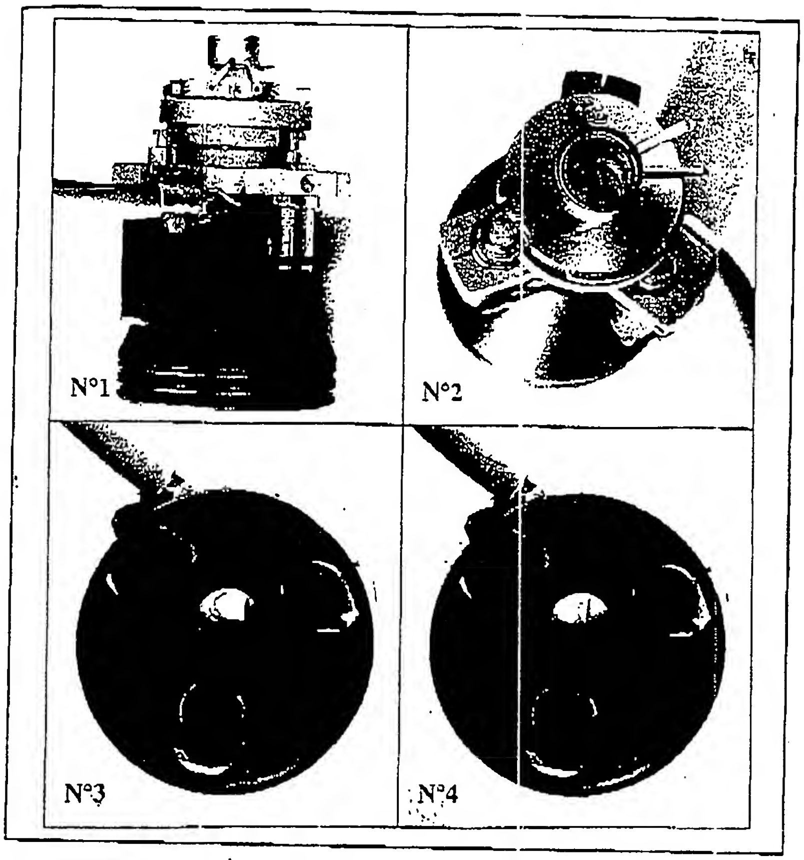

Figure 1: Four views of the presbyopia ablation mask. The two blunt blades are seen from the patient perspective (No° 2) and from the surgeon's perspective (No° 3, 4).

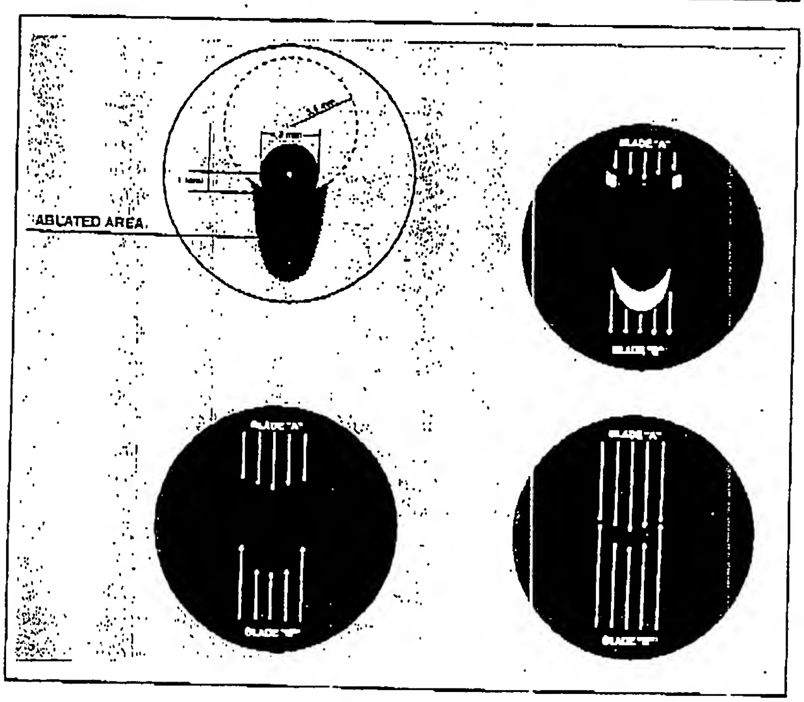

Figure 2: Sequence of events as the two blades slide over each other.

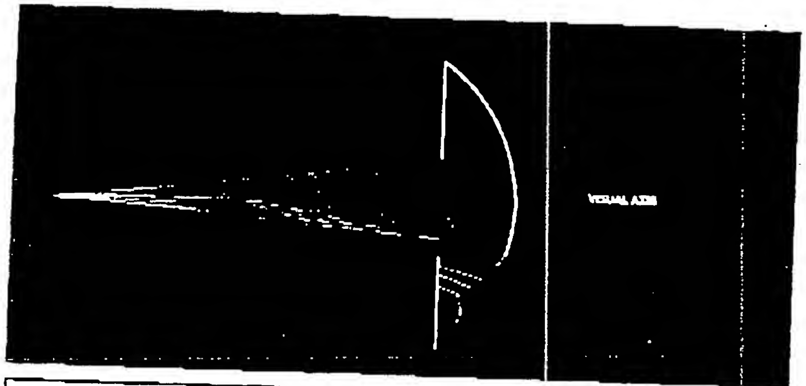

Figure 3: Diagram illustrating the curvature responsible for the desired optical effect (A), and the transition zone (B).

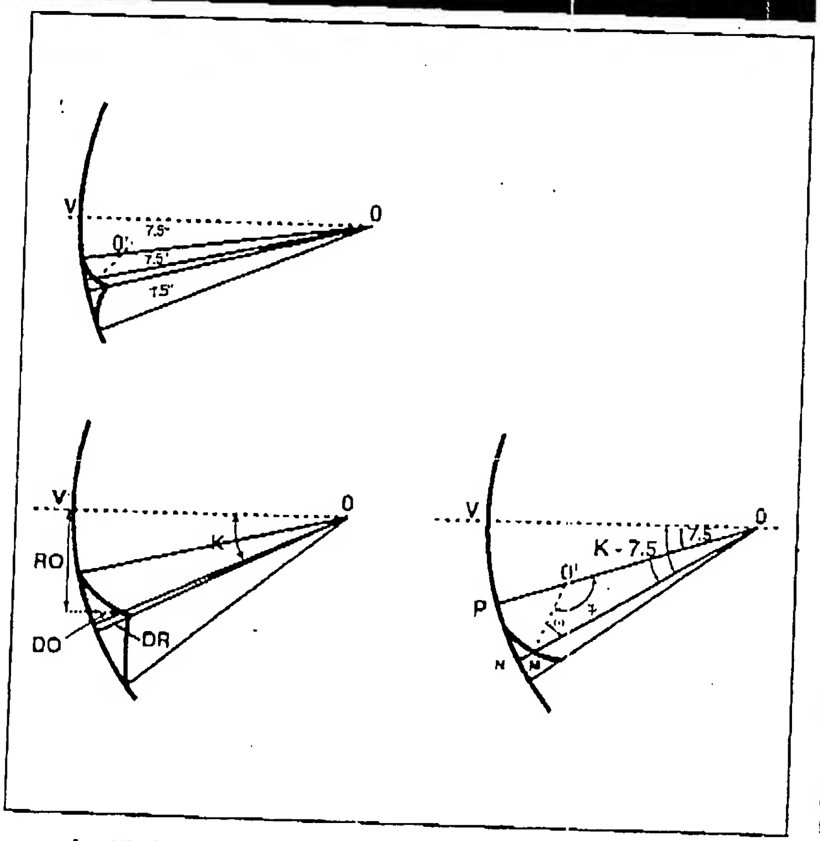

Figure 4: Diagram illustrating the basis for the calculations made to determine the angle subtended by the light rays refracted by the presbyopic zone ablated in the procedure. OV is the optical visual axis; RO the distance between the optical axis and the beginning of the ablation area; DO is the horizontal ablation depth; DR is the maximum ablation depth, measured perpendicular to the corneal surface; K is the subtended angle, which varies in relation to the corresponding ablation point on the surface. The additional elements used for the calculations are also shown. OP [= R] represents the curvature of the anterior corneal surface (R = 7.7 for the emmetropic Gullstrand eye); MN = R - OM is the (variable) ablation depth, measured perpendicular to the corneal surface; O'P is the radius of curvature of the corneal surface to be ablated; j = MO'O and w = O'MO are the angles used in the calculation.
Applying the sine theorem to the OO'M triangle, we obtain:

$$\frac{O'M}{\sin(K-7.5°)} = \frac{OO'}{\sin w}$$

where O'M = (n-1) / P, with n representing the refractive index of the cornea (1.376), P the dioptric power, and O'O = R - O'P = R - O'M.
A simple correlation is thus obtained between MN = R - OM = 7.7 - OM (in mm) and K, and this formula is then used to program the laser for the presbyopic correction.

corneal epithelium in the treatment area was abraded with a spatula (leaving the remaining epithelium to act as a protective layer against undesired ablation), the special presbyopia mask (Fig 1), in maximum aperture mode, was affixed on the eye with a suction of 660 millibar.

The diaphragm of the mask was then closed until blade A reached the previously marked pupillary center. Both blades were then closed by an additional 1.0 mm. A digital display shows the maximum distance between the two blades. With this value in hand, nomograms are used to indicate the ablation depth required, the number of ablation steps, and the number of scans needed for a given attempted correction. About 20 blade closure steps are required for the procedure.

In all eyes treated, a presbyopic correction of 3.00 D was planned. Postoperative treatment consisted of topical gentamycin three times daily and patching until complete reepithelialization. No corticosteroids were given at any time.

Follow-up examinations were scheduled for days 1 through 7, and day 15. Thereafter, examinations were performed by an independent observer at 1, 2,

3, 6, 12, 18, and 24 months postoperatively. In addition to near and distance visual acuity and manifest refraction, cycloplegic refraction, videokeratography, tonometry, and slit-lamp examination of the cornea and anterior segment were performed at each examination during the immediate postoperative period. Contrast sensitivity was tested at 1 week and at 1, 3, and 6 months after surgery using Regan charts at 95%, 50%, 25%, and 11% contrast levels.

Subepithelial corneal haze was graded clinically on a scale of 0 to 5 according to the McDonald scale.[4] Serial corneal topography was performed with the EyeSys Corneal Analysis System (EyeSys Laboratories Inc., Houston, Tx). One of the treated eyes was also analyzed with the Topographic Modeling System (Computed Anatomy Inc., New York, NY).

Informed consent was obtained from the patients after a detailed description of the procedure and a thorough review of the known risks. The Hospital's Ethics Committee approved the treatments.

RESULTS

In all three eyes, corneal reepithelialization was complete by 36 hours after surgery. Uncorrected and spectacle-corrected visual acuity remained unchanged (Table 1).

All three patients demonstrated a measurable presbyopic correction as early as 48 hours after surgery. After a regression of 1.00 D (Table 1), the presbyopic correction remained stable for the duration of the 24-month follow-up. The patients were able to read Jaeger 3 at 35 cm, in normal ambient illumination, without any near correction. All three patients also accepted a +2.50 D correction when using the uncorrected cornea for the near vision.

Since the ablated zone represents only about 15% of the total area of a 3.0-mm pupil, all three eyes were also able to read with their preoperative presbyopic correction (using the untreated 85% of the pupillary area).

A mild haze (grade 1) developed in the treated area within 2 weeks but disappeared after about 2 months (Table 1).

Contrast sensitivity, measured with Regan charts (96%, 50%, 25%, and 11% contrast), remained unchanged for the three highest contrasts when compared to the preoperative values (Table 2). There was some loss of contrast sensitivity when tested with the 11% chart.

Videokeratographic images confirmed corneal steepening corresponding to the correction obtained (Figs 5-7).

Table 2
Mean Contrast Sensitivity Values (Number of Lines Read) on Regan Charts for Three Eyes of Three Patients after PRK for Presbyopia

		Time after Surgery			
	Baseline	1 wk	1 mo	3 mo	6 mo
96% chart	9.8	9.5	9.4	9.7	9.7
50% chart	8.8	8.6	8.6	8.8	8.7
25% chart	6.5	4.4	4.6	4.6	4.5
11% chart	5.3	4.4	4.6	4.6	4.5

Note: Charts were placed against an opaque black background and two light sources of 150 watts each were positioned 1 meter from the chart. Total number of lines on chart was 11.

DISCUSSION

Some patients have difficulties accepting or using standard presbyopia corrections. Multifocal spectacles are not tolerated by everyone, and in some professions the visual field restrictions caused by presbyopia spectacles are perceived as disturbing. As PRK becomes more widespread, it is apparent that there is no satisfactory refractive procedure geared for specific correction of presbyopia.

This method incorporates an important safety feature in that the epithelium, left intact at the pupillary center, acts as a protective shield. Accidental upward decentration during zonal photoablation will therefore not cause any refractive change at the pupillary center.

Unlike the Anschutz refractive procedure for presbyopia[5], this method does not cause a decrease in contrast sensitivity at 96%, 50%, and 25% contrast, and only a slight decrease at 11% contrast. This is probably because only about 15% of the light that enters a 3.0-mm pupil passes through the treated zone, whereas 50% of the light passes through the zone created in other methods.[6]

An especially attractive feature of the procedure, particularly with regard to wound healing and postoperative optical clarity of the cornea, is that only a very superficial ablation (10 to 17 μm) is required. Only Bowman's membrane is altered and this probably explains why the subepithelial haze disappears so fast.

Another advantage of this method is that if a treated patient wants to hold a text at a reading distance closer than normal, a standard presbyopic spectacle correction can be used. The intact (major) part of the pupillary area is then utilized, while the image produced by the ablated zone is suppressed.

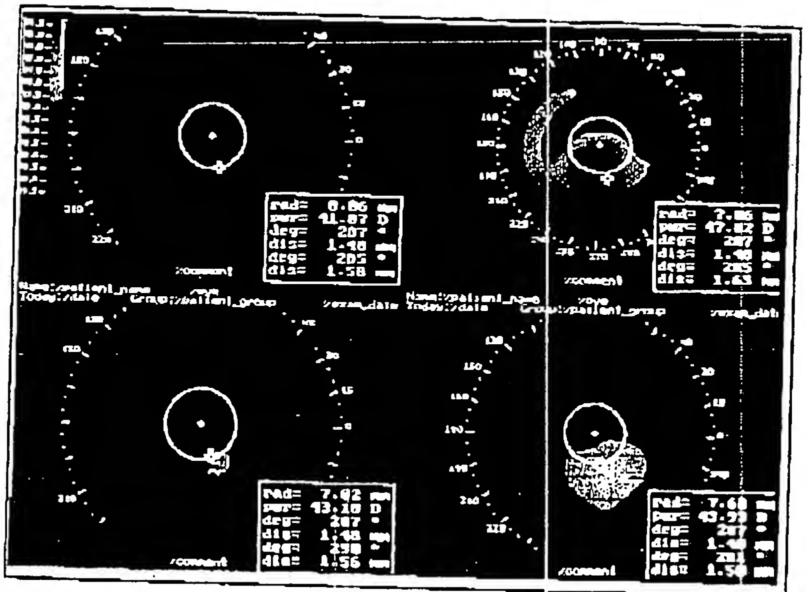

Figure 5: The upper left videokeratograph (EyeSys) shows the preoperative topography of patient O.M., the upper right was taken 3 days after surgery, the lower left 1 month after surgery, and the lower right 1 year after treatment. The immediate postoperative steepening was almost 6.00 D. By 1 month, the presbyopic correction was within 0.25 D of planned correction and remained unchanged at 1 year. The 1-year videokeratograph shows the area treated for the presbyopic correction. It also shows a slight nasal decentration of 0.63 mm.

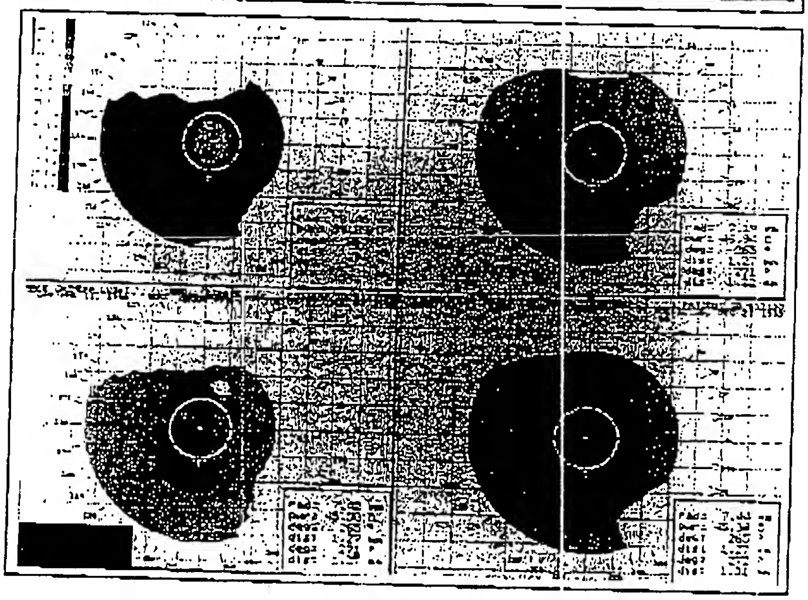

Figure 6: The upper left videokeratograph (EyeSys) shows the preoperative topography of patient C.L., the upper right was taken 3 days after surgery, the lower left 1 month after surgery, and the lower right 18 months after treatment. The immediate postoperative steepening was about 7.00 D. By 1 month, the presbyopic correction was within 0.25 D of planned and remained unchanged at 1 year. The last videokeratograph shows the crescent-shaped area treated for the presbyopic correction.

Additional advantages are the need for only a small zone to be ablated, the resultant rapid epithelialization, and the refractive effectiveness of the zonal presbyopic ablation for pupil diameters of up to 6 mm.

Drawbacks include the extreme precision required by this procedure (although final centration refinement with the motorized X-Y movement of the mask simplifies achievement of this precision). Incorrect delineation of the ablation zone can lead to suboptimal presbyopic correction. Inaccurate marking of the pupillary center, with upward displacement of the treatment zone, can impair spectacle-corrected visual acuity.

Also, some patients may need time to adjust to this zonal correction, just like most presbyopes struggle for a while when they are first fit with multifocal spectacles. However, the three patients reported here adapted immediately to the use of the corrected zone. They especially appreciated the wide visual field obtained with the laser procedure, compared with the restricted one they had with spectacles.

A further drawback is the decrease of presbyopic correction if the pupil dilates to more than 6.0 mm,

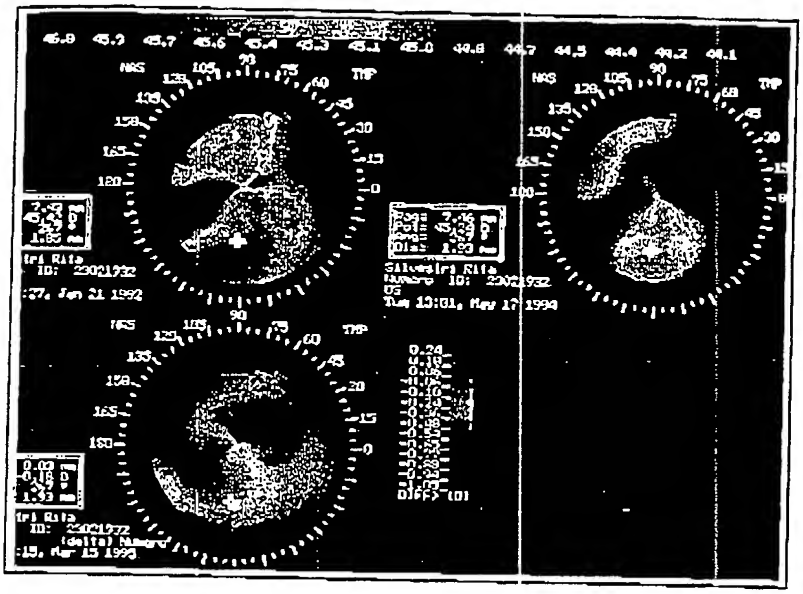

Figure 7: The upper left videokeratograph (EyeSys) shows the 1-month postoperative topography of patient S.R., the upper right was taken at 18 months postoperatively. The lower left videokeratograph shows the difference between these two maps. The color-coded scale shows that only a 0.25 D change occurred in the ablated area between month 1 and month 18.

or if it becomes decentered following intraocular surgery performed after the zonal ablation. When the pupil dilates to a diameter larger than the presbyopic ablation zone, the patient looking at a near object is only marginally disturbed by the unfocused image created by the surrounding untreated area. Only the upper part of the treated zone—the part which exhibits the increase in corneal curvature—produces the presbyopia correction.

In view of the fact that only three eyes have been treated, further studies are needed to verify the method's safety, predictability, and long-term refractive stability.

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